**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION**
**DECISION SUMMARY**
**DEVICE ONLY TEMPLATE**

**A. 510(k) Number:** k033387

**B. Analyte:** Quality Control material for multiple analytes

**C. Type of Test:** N/A

**D. Applicant:** Bio-Rad Laboratories

**E. Proprietary and Established Names:** Quest Diagnostics Serum Chemistry Control

**F. Regulatory Information:**

1. Regulation section: 21 CFR 862.1660

2. Classification: Class I

3. Product Code: JJY

4. Panel: 75

**G. Intended Use:**

1. Intended use(s): Quest Diagnostics Serum Chemistry Control is intended for use as a quality control serum to monitor the precision of an individual laboratory's automated and manual testing procedures.

2. Indication(s) for use: Quest Diagnostics Serum Chemistry Control is for use as a quality control serum to monitor the precision of an individual laboratory's automated and manual-testing procedures.

3. Special condition for use statement(s): none stated

4. Special instrument Requirements: Olympus AU5200; AU5400

**H. Device Description:** Quest Diagnostics Serum Chemistry Control is prepared from human serum to which purified biochemical materials (tissue extracts of human serum and animal origin), chemicals, preservatives, and stabilizers have been added.

**I. Substantial Equivalence Information:**

1. Predicate device name(s): Bio-Rad Laboratories Liquid Assayed Multiqual Control

2. Predicate K number(s): k011867

3. Comparison with predicate:

| Similarities & Differences | | |
|---|---|---|
| **Item** | **Device** | **Predicate** |
| Characteristics | Quest Diagnostics Serum Chemistry Control | Bio-Rad Liquid Assayed Muliqual Control |
| Intended Use | Quest Diagnostics Serum Chemistry Control is intended for use in clinical laboratories as a portion of Quality Assurance to aid in the maintenance of accuracy and precision in the clinical chemistry laboratory. | Liquid Assayed Muliqual Control is intended for use in clinical laboratories as an assayed quality control serum to monitor the precision of laboratory procedures listed in the package insert. |
| Form | Liquid | Liquid |
| Matrix | Human serum based plasma | Human serum based plasma |
| Other ingredients | Stabilizers and preservatives | Stabilizers and preservatives |
| Storage | $-10^0$C to $-20^0$C Until expiration date | $-20^0$C r colder Until expiration date |
| Open Vial claim | 10 days at 2-8$^0$C | 14 days at 2-8$^0$C |
| Storage | No Claim | 30 days at 2-8$^0$C |
| Analytes | ALT, Albumin, Alkaline Phosphatase, Amylase, AST, Direct Bilirubin, Total Bilirubin, Blood Urea Nitrogen, Calcium, Chloride, Cholesterol, HDL-C, CO2, Creatine Kinase, Gamma – Glutamyltransferase, Glucose, Iron, Lactate Dehydrogenase, Lipase, Magnesium, Phosphorus, | The predicate device contains other specific analytes not included in the new product. |

| | | |
|---|---|---|
| | Potassium, Sodium, T3 Uptake, T4, Total Protein, Triglycerides, Iron-Binding capacity, Unsaturated Iron Binding Capacity, Uric Acid. | |

**J. Standard/Guidance Document Referenced (if applicable):** None Stated

**K. Test Principle:** N/A

**L. Performance Characteristics (if/when applicable):**

1. Analytical performance:

*a. Precision/Reproducibility:* N/A

*b. Linearity/assay reportable range:* N/A

*c. Traceability (controls, calibrators, or method):* None Referenced

*d. Detection limit:* N/A

*e. Analytical specificity:* N/A

*f. Assay cut-off:* N/A

2. Comparison studies:

*a. Method comparison with predicate device:* N/A

*b. Matrix comparison:* Quest Diagnostics Serum Chemistry Control is prepared from human serum to which purified biochemical materials (tissue extracts of human serum and animal origin), chemicals, preservatives, and stabilizers have been added.

3. Clinical studies:

*a. Clinical sensitivity:* N/A

*b. Clinical specificity:* N/A

*c. Other clinical supportive data (when a and b are not applicable):* N/A

4. Clinical cut-off: N/A

5. Expected values/Reference range: N/A

**M. Conclusion:** Based upon the information provided, I recommend that the Quest Diagnostics Serum Chemistry Control for multiple analytes be found substantially equivalent to the predicate device.